February 26, 2016

ENGROSSED
SENATE BILL No. 41

DIGEST OF SB 41 (Updated February 24, 2016 11:05 am - DI 97)

Citations Affected: IC 5-10; IC 27-8; IC 27-13.

Synopsis: Pharmacy benefits. Requires a state employee health plan, an accident and sickness insurer, and a health maintenance organization to make available a procedure for a covered individual's use in requesting an exception to a step therapy protocol used by the state employee health plan, accident and sickness insurer, or health maintenance organization with respect to coverage for certain prescription drugs, including time frames for a determination concerning an exception and reasons for granting an exception.

Effective: July 1, 2016.

Crider, Brown L, Stoops,
Randolph Lonnie M

(HOUSE SPONSORS — CARBAUGH, KIRCHHOFER, BROWN C, HEATON)

January 5, 2016, read first time and referred to Committee on Rules & Legislative Procedure.
January 11, 2016, amended; reassigned to Committee on Health & Provider Services.
January 21, 2016, amended, reported favorably — Do Pass.
January 28, 2016, read second time, amended, ordered engrossed.
January 29, 2016, engrossed.
February 1, 2016, read third time, passed. Yeas 50, nays 0.

HOUSE ACTION

February 8, 2016, read first time and referred to Committee on Insurance.
February 25, 2016, amended, reported — Do Pass.

February 26, 2016

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

ENGROSSED
SENATE BILL No. 41

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 5-10-8-17 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 17. (a) As used in this section, "covered individual" means an individual entitled to coverage under a state employee health plan.**

(b) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to a covered individual's condition:

(1) to improve, preserve, or slow the deterioration of the covered individual's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the covered individual's condition or injury.

(c) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat a covered individual's condition; and

(2) as a result of the treatment under subdivision (1),

determined to be inappropriate to treat the covered individual's condition;

as a condition of coverage under a state employee health plan for succeeding treatment with another prescription drug.

(d) As used in this section, "protocol exception" means a determination by a state employee health plan that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular covered individual's condition; and

(2) the state employee health plan will:

(A) not require the covered individual's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the covered individual.

(e) As used in this section, "state employee health plan" refers to the following that provide coverage for prescription drugs:

(1) A self-insurance program established under section 7(b) of this chapter.

(2) A contract with a prepaid health care delivery plan that is entered into or renewed under section 7(c) of this chapter.

The term includes a person that administers prescription drug benefits on behalf of a state employee health plan.

(f) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a state employee health plan, the order in which certain prescription drugs must be used to treat a covered individual's condition.

(g) As used in this section, "urgent care situation" means a covered individual's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the covered individual's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the covered individual to severe pain that cannot be adequately managed, based on the covered

individual's treating health care provider's judgment.

(h) A state employee health plan shall publish on the state employee health plan's Internet web site, and provide to a covered individual in writing, a procedure for the covered individual's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which a covered individual may request a protocol exception.

(2) That the state employee health plan shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the covered individual.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the covered individual.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.

(C) The covered individual has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the covered individual because the covered individual's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care;

(ii) worsen a comorbid condition of the covered individual; or

(iii) decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the state employee health plan shall notify the covered individual and the covered individual's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the state employee health plan shall provide to the covered individual and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the state employee health plan may request a copy of relevant documentation from the covered individual's medical record in support of a protocol exception.

SECTION 2. IC 5-10-8-18 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 18. (a) The definitions in section 17 of this chapter apply throughout this section.**

(b) This section applies to a state employee health plan that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) A state employee health plan shall not remove a prescription drug from the state employee health plan's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the state employee health plan does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time a covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the covered individual:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 3. IC 27-8-5-30 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 30. (a) As used in this section, "insured" means an individual who is entitled to coverage under a policy of accident and sickness insurance.**

(b) As used in this section, "insurer" refers to an insurer that issues a policy of accident and sickness insurance. The term includes a person that administers prescription drug benefits on behalf of an insurer.

(c) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to an insured's condition:

(1) to improve, preserve, or slow the deterioration of the insured's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the insured's condition or injury.

(d) As used in this section, "policy of accident and sickness insurance" means a policy of accident and sickness insurance that provides coverage for prescription drugs.

(e) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an insured's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the insured's condition;

as a condition of coverage under a policy of accident and sickness insurance for succeeding treatment with another prescription drug.

(f) As used in this section, "protocol exception" means a determination by an insurer that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular insured's condition; and

(2) the insurer will:

(A) not require the insured's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the insured.

(g) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under a policy of accident and sickness insurance, the order in which certain prescription drugs must be used to treat an insured's condition.

(h) As used in this section, "urgent care situation" means an insured's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the insured's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the insured to severe pain that cannot be adequately managed, based on the insured's treating health care provider's judgment.

(i) An insurer shall publish on the insurer's Internet web site, and provide to an insured in writing, a procedure for the insured's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an insured may request a protocol exception.

(2) That the insurer shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the insured.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.

(C) The insured has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the insured because the insured's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

(ii) worsen a comorbid condition of the insured; or

(iii) decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the insurer shall notify the insured and the insured's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the insurer shall provide to the insured and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

SECTION 4. IC 27-8-5-31 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 31. (a) The definitions in section 30 of this chapter apply throughout this section.**

(b) This section applies to an insurer that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) An insurer shall not remove a prescription drug from the insurer's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review

requirements that apply to a prescription drug unless the insurer does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the insured:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

SECTION 5. IC 27-13-7-23 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 23. (a) As used in this section, "group contract" refers to a group contract that provides coverage for prescription drugs.**

(b) As used in this section, "health maintenance organization" refers to a health maintenance organization that provides coverage for prescription drugs. The term includes the following:

(1) A limited service health maintenance organization.

(2) A person that administers prescription drug benefits on behalf of a health maintenance organization or a limited service health maintenance organization.

(c) As used in this section, "individual contract" refers to an individual contract that provides coverage for prescription drugs.

(d) As used in this section, "medical necessity" or "medically necessary" means appropriateness, or appropriate, under the standard of care that applies to an enrollee's condition:

(1) to improve, preserve, or slow the deterioration of the enrollee's health, life, or function; or

(2) for the early screening, prevention, evaluation, diagnosis, or treatment of the enrollee's condition or injury.

(e) As used in this section, "preceding prescription drug" means a prescription drug that, according to a step therapy protocol, must be:

(1) first used to treat an enrollee's condition; and

(2) as a result of the treatment under subdivision (1), determined to be inappropriate to treat the enrollee's condition;

as a condition of coverage under an individual contract or a group

contract for succeeding treatment with another prescription drug.

(f) As used in this section, "protocol exception" means a determination by a health maintenance organization that, based on a review of a request for the determination and any supporting documentation:

(1) a step therapy protocol is not medically appropriate for treatment of a particular enrollee's condition; and

(2) the health maintenance organization will:

(A) not require the enrollee's use of a preceding prescription drug under the step therapy protocol; and

(B) provide immediate coverage for another prescription drug that is prescribed for the enrollee.

(g) As used in this section, "step therapy protocol" means a protocol that specifies, as a condition of coverage under an individual contract or a group contract, the order in which certain prescription drugs must be used to treat an enrollee's condition.

(h) As used in this section, "urgent care situation" means an enrollee's injury or condition about which the following apply:

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the enrollee's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the enrollee to severe pain that cannot be adequately managed, based on the enrollee's treating health care provider's judgment.

(i) A health maintenance organization shall publish on the health maintenance organization's Internet web site, and provide to an enrollee in writing, a procedure for the enrollee's use in requesting a protocol exception. The procedure must include the following provisions:

(1) A description of the manner in which an enrollee may request a protocol exception.

(2) That the health maintenance organization shall make a determination concerning a protocol exception request, or an appeal of a denial of a protocol exception request, not more than:

(A) in an urgent care situation, one (1) business day after receiving the request or appeal; or

(B) in a nonurgent care situation, three (3) business days after receiving the request or appeal.

(3) That a protocol exception will be granted if any of the following apply:

(A) A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the enrollee.

(B) A preceding prescription drug is expected to be ineffective, based on both of the following:

(i) The known clinical characteristics of the enrollee.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.

(C) The enrollee has previously received:

(i) a preceding prescription drug; or

(ii) another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug;

and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

(D) Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the enrollee because the enrollee's use of the preceding prescription drug is expected to:

(i) cause a significant barrier to the enrollee's adherence to or compliance with the enrollee's plan of care;

(ii) worsen a comorbid condition of the enrollee; or

(iii) decrease the enrollee's ability to achieve or maintain reasonable functional ability in performing daily activities.

(4) That when a protocol exception is granted, the health maintenance organization shall notify the enrollee and the enrollee's health care provider of the authorization for coverage of the prescription drug that is the subject of the protocol exception.

(5) That if:

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the health maintenance organization shall provide to the enrollee and

the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

SECTION 6. IC 27-13-38-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 7. (a) The definitions in IC 27-13-7-23 apply throughout this section.**

(b) A health maintenance organization shall not remove a prescription drug from the health maintenance organization's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review program requirements that apply to a prescription drug unless that health maintenance organization does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the enrollee:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.

COMMITTEE REPORT

Madam President: The Senate Committee on Rules and Legislative Procedure, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Delete the title and insert the following:

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Delete everything after the enacting clause and insert the following:

(SEE TEXT OF BILL)

and when so amended that said bill be reassigned to the Senate Committee on Health & Provider Services.

(Reference is to SB 41 as introduced.)

LONG, Chairperson

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 41, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 4, line 19, delete ":" and insert "**, as determined by the covered individual's treating health care provider:**".

Page 8, line 6, delete ":" and insert "**, as determined by the insured's treating health care provider:**".

Page 11, line 38, delete ":" and insert "**, as determined by the enrollee's treating health care provider:**".

and when so amended that said bill do pass.

(Reference is to SB 41 as printed January 12, 2016.)

MILLER PATRICIA, Chairperson

Committee Vote: Yeas 10, Nays 1.

SENATE MOTION

Madam President: I move that Senate Bill 41 be amended to read as follows:

Page 1, line 3, delete "(a) As used in this section, "clinical practice".

Page 1, delete lines 4 through 6.

Page 1, line 7, delete "(b)" and insert "**(a)**".

Page 1, delete lines 9 through 10.

Page 1, line 11, delete "(d)" and insert "**(b)**".

Page 2, line 1, delete "(e)" and insert "**(c)**".

Page 2, line 10, delete "(f)" and insert "**(d)**".

Page 2, line 21, delete "(g)" and insert "**(e)**".

Page 2, line 29, delete "(h)" and insert "**(f)**".

Page 2, delete lines 33 through 42.

Page 3, delete lines 1 through 39.

Page 3, line 40, delete "(k)" and insert "**(g)**".

Page 4, delete lines 13 through 17.

Page 4, line 18, delete "(4)" and insert "**(3)**".

Page 4, line 21, delete "Following the step therapy protocol" and insert "**A preceding prescription drug**".

Page 4, line 42, delete "(5)" and insert "**(4)**".

Page 5, line 5, delete "(l)" and insert "**(h)**".

Page 5, delete lines 17 through 18.

Page 5, line 21, delete "(a) As used in this section, "clinical practice".

Page 5, delete lines 22 through 26.

Page 5, line 27, delete "(c)" and insert "**(a)**".

Page 5, line 30, delete "(d)" and insert "**(b)**".

Page 5, line 34, delete "(e)" and insert "**(c)**".

Page 5, line 41, delete "(f)" and insert "**(d)**".

Page 6, line 2, delete "(g)" and insert "**(e)**".

Page 6, line 12, delete "(h)" and insert "**(f)**".

Page 6, line 22, delete "(i)" and insert "**(g)**".

Page 6, delete lines 26 through 42.

Page 7, delete lines 1 through 30.

Page 7, line 31, delete "(l)" and insert "**(h)**".

Page 8, delete lines 2 through 5.

Page 8, line 6, delete "(4)" and insert "**(3)**".

Page 8, line 9, delete "Following the step therapy protocol" and insert "**A preceding prescription drug**".

Page 8, line 30, delete "(5)" and insert "**(4)**".

Page 8, line 34, delete "(m)" and insert "**(i)**".

Page 9, delete lines 4 through 5.

Page 9, line 8, delete "(a) As used in this section, "clinical practice".

Page 9, delete lines 9 through 11.

Page 9, line 12, delete "(b)" and insert "**(a)**".

Page 9, line 14, delete "(c)" and insert "**(b)**".

Page 9, line 21, delete "(d)" and insert "**(c)**".

Page 9, line 23, delete "(e)" and insert "**(d)**".

Page 9, line 30, delete "(f)" and insert "**(e)**".

Page 9, line 39, delete "(g)" and insert "**(f)**".

Page 10, line 8, delete "(h)" and insert "**(g)**".

Page 10, delete lines 12 through 42.

Page 11, delete lines 1 through 18.

Page 11, line 19, delete "(k)" and insert "**(h)**".

Page 11, delete lines 34 through 38.

Page 11, line 39, delete "(4)" and insert "**(3)**".

Page 11, line 42, delete "Following the step therapy protocol" and insert "**A preceding prescription drug**".

Page 12, line 21, delete "(5)" and insert "**(4)**".

Page 12, line 26, delete "(m)" and insert "**(i)**".

Page 12, delete lines 38 through 39.

(Reference is to SB 41 as printed January 22, 2016.)

CRIDER

COMMITTEE REPORT

Mr. Speaker: Your Committee on Insurance, to which was referred Senate Bill 41, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 2, between lines 27 and 28, begin a new paragraph and insert:

"**(g) As used in this section, "urgent care situation" means a covered individual's injury or condition about which the following apply:**

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the covered individual's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the covered individual to severe pain that cannot be adequately managed, based on the covered individual's treating health care provider's judgment.".

Page 2, line 28, delete "(g)" and insert "**(h)**".

Page 2, line 39, delete "the case of an emergency, twenty-four (24) hours" and insert "**an urgent care situation, one (1) business day**".

Page 2, line 41, delete "the case of a nonemergency, seventy-two (72) hours" and insert "**a nonurgent care situation, three (3) business days**".

Page 3, line 2, delete ", as determined by the covered individual's" and insert "**:**".

Page 3, delete line 3.

Page 3, delete lines 8 through 10, begin a new line double block indented and insert:

"**ineffective, based on both of the following:**

(i) The known clinical characteristics of the covered individual.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.".

Page 3, line 19, delete "medical necessity," and insert "**clinical appropriateness,**".

Page 3, line 20, delete "." and insert "**because the covered individual's use of the preceding prescription drug is expected to:**

(i) cause a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care;

(ii) worsen a comorbid condition of the covered individual; or

(iii) decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.".

Page 3, delete lines 21 through 24.

Page 3, delete lines 30 through 41, begin a new line block indented and insert:

"**(5) That if:**

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the state

employee health plan shall provide to the covered individual and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the state employee health plan may request a copy of relevant documentation from the covered individual's medical record in support of a protocol exception.

SECTION 2. IC 5-10-8-18 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 18. (a) The definitions in section 17 of this chapter apply throughout this section.**

(b) This section applies to a state employee health plan that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) A state employee health plan shall not remove a prescription drug from the state employee health plan's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the state employee health plan does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time a covered individual for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the covered individual:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.".

Page 4, after line 42, begin a new paragraph and insert:

"**(h) As used in this section, "urgent care situation" means an insured's injury or condition about which the following apply:**

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the insured's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than

the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the insured to severe pain that cannot be adequately managed, based on the insured's treating health care provider's judgment.".

Page 5, line 1, delete "(h)" and insert "**(i)**".

Page 5, line 10, delete "the case of an emergency, twenty-four (24) hours" and insert "**an urgent care situation, one (1) business day**".

Page 5, line 12, delete "the case of a nonemergency, seventy-two (72) hours" and insert "**a nonurgent care situation, three (3) business days**".

Page 5, line 15, delete ", as determined by the insured's treating" and insert "**:**".

Page 5, delete line 16.

Page 5, delete lines 21 through 23, begin a new line double block indented and insert:

"**ineffective, based on both of the following:**

(i) The known clinical characteristics of the insured.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.".

Page 5, line 32, delete "medical necessity," and insert "**clinical appropriateness,**".

Page 5, line 33, delete "." and insert "**because the insured's use of the preceding prescription drug is expected to:**

(i) cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

(ii) worsen a comorbid condition of the insured; or

(iii) decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.".

Page 5, delete lines 34 through 37.

Page 5, delete line 42, begin a new line block indented and insert:

"**(5) That if:**

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the insurer shall provide to the insured and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support

of a protocol exception.".

Page 6, delete lines 1 through 11, begin a new paragraph and insert:

"SECTION 4. IC 27-8-5-31 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 31. (a) The definitions in section 30 of this chapter apply throughout this section.**

(b) This section applies to an insurer that uses a formulary, cost sharing, or utilization review for prescription drug coverage.

(c) An insurer shall not remove a prescription drug from the insurer's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review requirements that apply to a prescription drug unless the insurer does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an insured for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the insured:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.".

Page 7, between lines 14 and 15, begin a new paragraph and insert:

"**(h) As used in this section, "urgent care situation" means an enrollee's injury or condition about which the following apply:**

(1) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could seriously jeopardize the enrollee's:

(A) life or health; or

(B) ability to regain maximum function;

based on a prudent layperson's judgment.

(2) If medical care or treatment is not provided earlier than the time frame generally considered by the medical profession to be reasonable for a nonurgent situation, the injury or condition could subject the enrollee to severe pain that cannot be adequately managed, based on the enrollee's treating health care provider's judgment.".

Page 7, line 15, delete "(h)" and insert "**(i)**".

Page 7, line 26, delete "the case of an emergency, twenty-four (24)

hours" and insert "**an urgent care situation, one (1) business day**".

Page 7, line 28, delete "the case of a nonemergency, seventy-two (72) hours" and insert "**a nonurgent care situation, three (3) business days**".

Page 7, line 31, delete ", as determined by the enrollee's treating" and insert "**:**".

Page 7, delete line 32.

Page 7, delete lines 37 through 39, begin a new line double block indented and insert:

"**ineffective, based on both of the following:**

(i) The known clinical characteristics of the enrollee.

(ii) Sound clinical evidence of the known characteristics of the prescription drug regimen.".

Page 8, line 6, delete "medical necessity," and insert "**clinical appropriateness,**".

Page 8, line 7, delete "." and insert "**because the enrollee's use of the preceding prescription drug is expected to:**

(i) cause a significant barrier to the enrollee's adherence to or compliance with the enrollee's plan of care;

(ii) worsen a comorbid condition of the enrollee; or

(iii) decrease the enrollee's ability to achieve or maintain reasonable functional ability in performing daily activities.".

Page 8, delete lines 8 through 11.

Page 8, delete lines 17 through 28, begin a new line block indented and insert:

"**(5) That if:**

(A) a protocol exception request; or

(B) an appeal of a denied protocol exception request;

results in a denial of the protocol exception, the health maintenance organization shall provide to the enrollee and the treating health care provider notice of the denial, including a detailed, written explanation of the reason for the denial and the clinical rationale that supports the denial.

(6) That the insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception.

SECTION 6. IC 27-13-38-7 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 7. (a) The definitions in IC 27-13-7-23 apply throughout this section.**

(b) A health maintenance organization shall not remove a

prescription drug from the health maintenance organization's formulary, change the cost sharing requirements that apply to a prescription drug, or change the utilization review program requirements that apply to a prescription drug unless that health maintenance organization does at least one (1) of the following:

(1) At least sixty (60) days before the removal or change is effective, send written notice of the removal or change to each enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period.

(2) At the time an enrollee for whom the prescription drug has been prescribed during the preceding twelve (12) month period requests a refill of the prescription drug, provide to the enrollee:

(A) written notice of the removal or change; and

(B) a sixty (60) day supply of the prescription drug under the terms that applied before the removal or change.".

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 41 as reprinted January 29, 2016.)

CARBAUGH

Committee Vote: yeas 11, nays 0.